EXHIBIT A

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
90/009,324	11/07/2008	6063563	T126 7002	5431

44444 7590 07/07/2009

BAXTER HEALTHCARE CORPORATION
ONE BAXTER PARKWAY
DF2-2E
DEERFIELD, IL 60015

EXAMINER	
ART UNIT	PAPER NUMBER

DATE MAILED: 07/07/2009

Please find below and/or attached an Office communication concerning this application or proceeding.

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CENTRAL REEXAMINATION UNIT

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(THIRD PARTY REQUESTER'S CORRESPONDENCE ADDRESS)

WOMBLE CARLYLE SANDRIDGE & RICE, PLLC

ATTN: PATENT DOCKETING

P.O. BOX 7037

ATLANTA, GA 30357-0037

EX PARTE REEXAMINATION COMMUNICATION TRANSMITTAL FORM

REEXAMINATION CONTROL NO. *90/009,324*.

PATENT NO. *6063563*.

ART UNIT *3991*.

Enclosed is a copy of the latest communication from the United States Patent and Trademark Office in the above identified *ex parte* reexamination proceeding (37 CFR 1.550(f)).

Where this copy is supplied after the reply by requester, 37 CFR 1.535, or the time for filing a reply has passed, no submission on behalf of the *ex parte* reexamination requester will be acknowledged or considered (37 CFR 1.550(g)).

Notice of Intent to Issue Ex Parte Reexamination Certificate	Control No.	Patent Under Reexamination	
	90/009,324	6063563	
	Examiner	Art Unit	
	BRENDA BRUMBACK	3991	

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

1. ☒ Prosecution on the merits is (or remains) closed in this *ex parte* reexamination proceeding. This proceeding is subject to reopening at the initiative of the Office or upon petition. *Cf.* 37 CFR 1.313(a). A Certificate will be issued in view of
   (a) ☒ Patent owner's communication(s) filed: *4/20/09 & 5/14/09*.
   (b) ☐ Patent owner's late response filed: _____.
   (c) ☐ Patent owner's failure to file an appropriate response to the Office action mailed: _____.
   (d) ☐ Patent owner's failure to timely file an Appeal Brief (37 CFR 41.31).
   (e) ☐ Other: _____.

   Status of *Ex Parte* Reexamination:
   (f) Change in the Specification: ☐ Yes ☒ No
   (g) Change in the Drawing(s): ☐ Yes ☒ No
   (h) Status of the Claim(s):
      (1) Patent claim(s) confirmed: *1-24*.
      (2) Patent claim(s) amended (including dependent on amended claim(s)): _____
      (3) Patent claim(s) cancelled: _____.
      (4) Newly presented claim(s) patentable: _____.
      (5) Newly presented cancelled claims: _____.

2. ☒ Note the attached statement of reasons for patentability and/or confirmation. Any comments considered necessary by patent owner regarding reasons for patentability and/or confirmation must be submitted promptly to avoid processing delays. Such submission(s) should be labeled: "Comments On Statement of Reasons for Patentability and/or Confirmation."

3. ☐ Note attached NOTICE OF REFERENCES CITED (PTO-892).

4. ☒ Note attached LIST OF REFERENCES CITED (PTO/SB/08).

5. ☐ The drawing correction request filed on _____ is: ☐ approved ☐ disapproved.

6. ☐ Acknowledgment is made of the priority claim under 35 U.S.C. § 119(a)-(d) or (f).
   a)☐ All b)☐ Some* c)☐ None of the certified copies have
   ☐ been received.
   ☐ not been received.
   ☐ been filed in Application No. _____.
   ☐ been filed in reexamination Control No. _____.
   ☐ been received by the International Bureau in PCT Application No. _____.

   * Certified copies not received: _____.

7. ☐ Note attached Examiner's Amendment.

8. ☐ Note attached Interview Summary (PTO-474).

9. ☐ Other: _____.

/BRENDA BRUMBACK/ Primary Examiner, Art Unit 3991	PADMASHRI PONNALURI PRIMARY EXAMINER CRU - AU 3991	DEBORAH D. JONES CRU SPE-AU 3991

cc: Requester (if third party requester)

REEXAMINATION

REASONS FOR PATENTABILITY / CONFIRMATION

Reexamination Control No. *90/009,324* Attachment to Paper No. *20090623*.

Art Unit *3991*.

See attached reasons for patentability confirmation.

/BRENDA BRUMBACK/ Primary Examiner, Art Unit 3991	PADMASHRI PONNALURI PRIMARY EXAMINER CRU - AU 3991	DEBORAH D. JONES CRU SPE-AU 3991

PTOL-476 (Rev. 03-98)

***Ex Parte* Reexamination**

Notice of Intent to Issue Reexamination Certificate

Procedural Posture

This is an *ex parte* reexamination of **U.S. Patent 6,063,563**, issued on 05/16/00 to Peddada *et al.* (the '563 Patent).

A First Office Action was mailed on 02/19/09.

Patent Owners' Response to the Nonfinal Office Action was filed on 04/20/09 with accompanying Phatarfod and Sudbury, Stramer, Smith, and Young Evidentiary Declarations. Patent Owner's Supplemental Response was filed on 05/14/09 with an accompanying evidentiary document in the form of a transcript from the March 13, 1997 session of the Fifty-Fourth Meeting of the Blood Products Advisory Committee of the Food and Drug Administration Center for Biologics Evaluation (the "FDA Meeting" document).

Information Disclosure Statements

The Information Disclosure Statements filed 2/20/09, 4/20/09, 5/14/09, 6/12/09, and 6/19/09 have all been considered. Signed copies are attached hereto. All documents filed with the IDS of 2/20/09 pertaining to Civil Action No. 5:08-CV-0028 and 5:08-CV-464-H were considered ; however, those documents have been lined through on the PTO/SB/08 form as not appropriate for printing on the face of the reexamination certificate.

Documents filed with the IDS of 4/20/09, 5/14/09, and 6/19/09 which were not in English have not been considered and are lined through, as there was no English translation or explanation of the relevance of the documents provided with the disclosure statements.

Each information disclosure statement must include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information listed that is not in the English language. If a complete translation of the information into English is submitted with the non-English language information, no concise explanation is required. An English-language equivalent application may be submitted to fulfill this requirement if it is, in fact, a translation of a foreign language application being listed in an information disclosure statement. Submission of an English language abstract of a reference may fulfill the requirement for a concise explanation (MPEP 1.97).

The '563 Patent Invention

Claims 1-24 of the '563 Patent are drawn to a method for **testing plasma donations in a single high-sensitivity test cycle**, comprising the steps of

defining an n-dimensional matrix, where n is an integer, the matrix further comprising a multiplicity of elements, each element defined by an intersection of the n-dimensions of the matrix, each individual element identified by a respective matrix notation, the matrix notation comprising at least an index for each dimension of the array;

taking a sample from each of the multiplicity of biological fluid donations;

mapping each sample to a respective particular one of each element of the matrix, each individual sample identified by its corresponding element's respective matrix notation;

taking aliquots from each sample, the number of aliquots taken from each sample defined by the number of dimensions characterizing the matrix;

forming subpools from the aliquots of each sample, each subpool containing an aliquot from all samples identified by a matrix notation in which one dimensional index is fixed, each respective subpool identified by said fixed dimensional index;

providing the subpools to a high-sensitivity testing facility, wherein **all of the subpools are tested for viral indication in a single high- sensitivity test cycle**;

determining the respective fixed dimensional indices of subpools which return a positive viral indication; and

combining said fixed dimensional indices into a matrix notation, thereby unambiguously identifying a unique matrix element defined by the matrix notation, thus unambiguously identifying a uniquely viral positive sample (emphasis added).

Withdrawn Claim Rejections

The rejection of claims 1, 2, 10, 20, and 23 under 35 U.S.C. 103(a) as unpatentable over Phatarfod in view of Atwood and the rejection of claims 3-9, 11-19, 21, 22, and 24 under 35 U.S.C. 103(a) as unpatentable over Phatarfod in view of Atwood and further in view of Kenny are withdrawn pursuant to Patent Owner's Arguments and the Evidentiary Declarations of Phatarfod and Sudbury, Stramer, Smith, and Young, which are persuasive.

STATEMENT OF REASONS FOR PATENTABILITY AND/OR CONFIRMATION

The following is an examiner's statement of reasons for patentability confirmation of claims 1-24 of US Patent 6,063,563 to Peddada et al. (the '563 patent).

The Declaration of Phatarfod and Sudbury, authors of the primary reference used to reject the claims in the Nonfinal Rejection mailed 02/19/09, provides evidence that Phatarfod *et al.* teach away from the critical feature of the present claims, which is testing blood donations for viral contamination in a single high sensitivity test cycle (or more specifically by a single PCR testing cycle). Phatarfod *et al.* attest to the fact that the testing steps set forth in the Phatarfod *et al.* reference were intended to be performed separately and sequentially. The single test cycle scheme, as is presently claimed, was not contemplated by Phatarfod *et al.* or in any of the other references of record.

Furthermore, the Stramer, Smith, and Young Declarations with the supporting FDA Meeting document (see Patent Owner's response of 5/14/09, page 2) provides evidence of nonobviousness of the claimed method and also of a long-felt need for a sensitive, rapid, and cost-effective means for screening blood donations, which was not met until the present invention. Furthermore, as is attested to by Stramer (see Paragraph 17 of the Stramer Declaration), because Kenny is directed to solving a different problem than the one addressed by the present invention, *i. e.*, identification and typing of a virus isolate using pooled antisera, the skilled virologist at the time of the invention would not have looked to Kenny to combine with Phatarfod, in order to arrive at the presently claimed method of forming a three dimensional array of pooled blood donations and testing those donations for viral contamination in a single high sensitivity test cycle (see patented claims 15-19 for example).

Conclusion

Claims 1-24 are confirmed.

Any comments considered necessary by PATENT OWNER regarding the above statement of reasons for patentability and/or confirmation must be submitted promptly to avoid processing delays. Such submission by the patent owner should be labeled: "Comments on Statement of Reasons for patentability and/or Confirmation" and will be placed in the reexamination file.

Future Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Brenda Brumback** whose telephone number **571-272-0961.** The examiner can normally be reached on Monday through Friday between 8:30 AM and 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor **Deborah Jones** can be reached on **571-272-1535**. The fax phone number for the organization where this application or proceeding is assigned is **571-273-9900**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free)i

All correspondence relating to this Ex parte Reexamination proceeding should be directed to:

By EFS:

Registered users may submit via the electronic filing system EFS-Web at

https://sportal.uspto.gov/authenticate/authenticateuserlocalepf.html

By Mail to:

Attn: Mail Stop "Ex Parte Reexam" Central Reexamination Unit Commissioner for Patents
P. O. Box 1450
Alexandria VA 22313-1450

By FAX to:
(571) 273-9900
Central Reexamination Unit

Hand-deliver any communications to:
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Randolph Building, Lobby Level
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Signed:

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